ANTISEPTIC - eucalyptol, menthol, methyl salicylate, thymol mouthwash
Duane Reade

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

active ingredient

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen guns, pus fro the gum line, loose teeth or increased spacing between the teeth. These may be signs of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- adults and children 12 years of age and older: vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonsful) between your teeth twice a day for 30 seconds then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use

Other information

- this rinse is not intended to replace brushing or flossing
- cold weather may cloud this product. Its antiseptic properties are not affected.

Store at room temperatures (59□-77□F)

Inactive ingredients

water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sucralose and/or sodium saccharin, sodium benzoate, propylene glycol alginate, FD&C yellow no. 6, FD&C blue no. 1

TEP

Sealed With Printed Neckband For Your Protection

principal display panel

vanilla mint

antiseptic mouthwash

for fresher breath

kills germs that cause bad breath, plaque and the gum disease gingivitis

1 liter 33.8 fl oz

ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67732-124
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67732-124-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2006	
2	NDC:67732-124-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/08/2006	

Labeler - Duane Reade (011988995)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(67732-124)